

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**PREMERA BLUE CROSS, on behalf of itself
and all others similarly situated,**

Plaintiff,

v.

**TAKEDA PHARMACEUTICAL COMPANY
LIMITED, TAKEDA PHARMACEUTICALS
U.S.A., INC., and TAKEDA
PHARMACEUTICALS AMERICA, INC.,**

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff Premera Blue Cross (“Premera”) brings this action on behalf of itself and all other similarly situated third-party payers (“TPPs”) against Defendants Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc. (collectively, “Takeda”). These allegations are based on personal knowledge, investigation of counsel, publicly available materials and knowledge, information, and belief.

INTRODUCTION

1. Since 2006, Takeda has marketed and sold Amitiza (lubiprostone), a constipation drug, in the United States. For nearly fifteen years, and for nearly seven years beyond the expiration of the patent covering Amitiza’s active pharmaceutical compound, Takeda held a monopoly in the lubiprostone market, making hundreds of millions of dollars in annual sales revenue.

2. Par Pharmaceutical, Inc. (“Par”) entered the market with a license to sell authorized generic Amitiza on January 4, 2021. Until January 1, 2023, the two companies maintained a duopoly.

3. This timeline does not reflect the ordinary operation of the United States Food and Drug Administration's ("FDA") approval process and federal patent litigation. Rather, Takeda, Takeda's partner Sucampo Pharmaceuticals, Inc. ("Sucampo"), and Par reached an agreement in September 2014 (the "2014 Takeda/Sucampo-Par Agreement") that artificially extended the period of Amitiza's brand exclusivity and ensured that, at the onset of generic competition, only one generic version could enter the market for at least six months, and up to two years.

4. The 2014 Takeda/Sucampo-Par Agreement, which is partly reflected in and partly obscured by a September 30, 2014 written settlement of Takeda and Sucampo's patent infringement suit against Par, restrained competition in the lubiprostone market and provided for a 50/50 division of profits earned from sales of the supra-competitively priced authorized generic Amitiza. Takeda, Sucampo, and Par's extra profits came at the direct expense of drug payers and consumers.

5. Four additional manufacturers have received FDA approval for generic Amitiza products, but each one agreed to a January 1, 2023 entry date following litigation with Takeda and Sucampo. As a result, the lubiprostone market remained restrained through the end of 2022, and the effects of the restraint are still being felt thereafter.

6. Takeda, Sucampo, and Par concealed the true nature of their agreement from the public, including Plaintiff Premera and Class members, by redacting crucial portions of their agreement in public filings and falsely representing to the court overseeing their patent infringement litigation that the agreement was "procompetitive." Plaintiff Premera and the Class did not discover, and could not have discovered, their injuries until at least January 2021, as further alleged below.

7. Because Plaintiff Premera and Class members were directly injured by Takeda and its co-conspirators' restraint of the market, Plaintiff Premera brings this action on behalf of itself

and all others similarly situated under state antitrust statutes, state consumer protection statutes, and state law governing unjust enrichment.

PARTIES

8. Plaintiff Premera Blue Cross is a health care services contractor incorporated in the State of Washington, with its principal place of business in Mountlake Terrace, Washington.

9. Defendant Takeda Pharmaceutical Company Limited (“Takeda Japan”) is a Japanese public stock corporation with its principal place of business in Tokyo, Japan. Takeda Japan is the largest pharmaceutical company in Asia.

10. Takeda Japan’s stock trade on the Tokyo Stock Exchange, and its American Depositary Receipts trade on the New York Stock Exchange as “TAK.” As of June 1, 2023, its market capitalization was \$50.5 billion.

11. Takeda Japan is a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

12. Defendant Takeda Pharmaceuticals U.S.A., Inc. (“Takeda USA”), a wholly owned subsidiary of Takeda Japan, is a Delaware corporation with its principal place of business located at 95 Hayden Avenue, Lexington, Massachusetts 02421.

13. Takeda Japan’s 2021 annual filing with the United States Securities and Exchange Commission (“SEC”) identifies Takeda USA as its “agent in the U.S. in connection with this annual report.”¹

14. Takeda USA is a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

15. Defendant Takeda Pharmaceuticals America, Inc. (“Takeda America”) is a Delaware

¹ Takeda Pharmaceutical Company Limited, Annual Report (Form 20-F) at 24 (June 29, 2021).

corporation with its principal place of business located at 95 Hayden Avenue, Lexington, Massachusetts 02421. Takeda America is a wholly owned subsidiary of Takeda U.S.A., and an indirect subsidiary of Takeda Japan.

16. Takeda America is a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

17. Takeda Japan’s website identifies the business address of Takeda USA and Takeda America as its own “U.S. Hub...for the U.S. Business Unit, Global R&D, ...”²

18. Non-Defendant co-conspirator Sucampo Pharmaceuticals, Inc. (“Sucampo”) is a Delaware corporation with its former principal places of business in Bethesda, Maryland and Bedminster, New Jersey. As further alleged below, Sucampo partnered with Takeda in the production and commercialization of Amitiza.

19. Sucampo is a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

20. Non-Defendant co-conspirator Sucampo GmbH f/k/a Sucampo AG is a Swiss limited liability company with its principal place of business in Zug, Switzerland. Sucampo GmbH is a wholly-owned subsidiary of Sucampo.

21. Sucampo GmbH is a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

22. Non-Defendant co-conspirator Sucampo Pharma Americas LLC is a Delaware corporation with its former principal places of business in Bethesda, Maryland and Bedminster, New Jersey. Sucampo Pharma Americas LLC is a wholly-owned subsidiary of Sucampo.

23. Non-Defendant co-conspirator R-Tech Ueno, Ltd. (“R-Tech Ueno”) was a Japanese public stock company with its principal place of business in Tokyo, Japan. Sucampo acquired R-

² Takeda Pharmaceutical Company Limited, “US Contact Information,” available at <https://www.takeda.com/en-us/who-we-are/contact-us/> (last accessed April 19, 2023).

Tech Ueno for \$275 million on December 7, 2015.

24. R-Tech Ueno was a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

25. Non-Defendant co-conspirator Mallinckrodt plc is an Irish public limited company with its principal place of business in Dublin, Ireland. Mallinckrodt acquired Sucampo in 2018 for \$1.2 billion. Mallinckrodt's December 26, 2017 press release announcing the Sucampo acquisition mentioned Amitiza thirteen times, celebrating the "near-term net sales and earnings accretion through AMITIZA."³ Mallinckrodt filed for Chapter 11 bankruptcy in October 2020.

26. Non-Defendant co-conspirator Par Pharmaceutical, Inc. ("Par") is a New York corporation with its principal place of business at 6 Ram Ridge Road, Chestnut Ridge, New York 10977. Par is a wholly owned subsidiary of Endo International plc, an Irish public limited company with its principal place of business in Dublin, Ireland.

27. Par is a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

28. Non-Defendant co-conspirator Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business at 6 Ram Ridge Road, Chestnut Ridge, New York 10977. It is a non-operating intermediate parent of Par and a wholly owned subsidiary of Endo International plc.

29. Par Pharmaceutical Companies, Inc. is a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

30. Non-Defendant co-conspirator Anchen Pharmaceuticals, Inc. ("Anchen") is a Delaware corporation with its principal place of business at 9601 Jeronimo Road, Irvine, California

³ News Release, Mallinckrodt Pharmaceuticals, Mallinckrodt to Acquire Sucampo Pharmaceuticals for Approximately \$1.2 Billion (Dec. 26, 2017), available at <https://www.mallinckrodt.com/about/news-and-media/news-detail/?id=8786> (last accessed April 19, 2023).

92618. As alleged below, Anchen was acquired by Par in November 2011 and is now a wholly-owned subsidiary of Endo International plc.

31. Anchen is a signatory party to the 2014 Takeda/Sucampo-Par Agreement.

32. Endo International plc filed for Chapter 11 bankruptcy in August 2022.

JURISDICTION AND VENUE

33. The Court has subject matter jurisdiction over all of Premera's claims under 28 U.S.C. § 1332(d), because Premera asserts these claims on behalf of a Class including members that are citizens of a state different than the state of any Defendant, and the matter in controversy exceeds \$5,000,000.

34. Venue is appropriate in this District under 28 U.S.C. § 1391(b) because Defendants and/or their agents may be found in this District and transact business within this District, and a substantial part of the events or omissions giving rise to the claim occurred within this District.

35. As alleged in further detail below, the Court has personal jurisdiction over each Defendant. Each Defendant maintained substantial contacts in the Commonwealth of Massachusetts and throughout the United States, each Defendant committed overt acts in furtherance of the unlawful scheme in the Commonwealth of Massachusetts and throughout the United States, and the scheme was directed at, and had the intended effect of, causing injury to persons residing in, located in, or doing business in the Commonwealth of Massachusetts and throughout the United States.

REGULATORY BACKGROUND

A. The Prescription Drug Marketplace

36. Takeda and its co-conspirators successfully restrained the United States market for lubiprostone by gaming the regulatory machinery of the FDA and the civil procedure of federal patent infringement litigation.

37. For most consumer products, the person responsible for paying is the consumer who selects the product. The pharmaceutical marketplace departs from this norm.

38. Prescription drugs may be dispensed only pursuant to a doctor's prescription, and a pharmacist may dispense only the brand-name drug named in the prescription or its AB-rated, FDA-approved generic equivalent.

39. In most instances, the patient and his or her health insurer pay for the prescription drug that a doctor has prescribed. Like the pharmacist, their "choice" is limited to the brand name drug named in the prescription or its AB-rated generic equivalent.

40. Therefore, the doctor's prescription defines the relevant product market because it limits the consumer's (and pharmacist's) choice to the drug named therein.

41. When there is no generic competition for a brand name drug, the brand manufacturers can set and maintain prices without losing market share. The ability to do this is the result of the brand name drug company's monopoly power over the market for that drug.

B. The Hatch-Waxman Act and FDA Approval Process.

42. Under the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301-392 ("FDCA"), a manufacturer that creates a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug and identify any patents claiming the drug. 21 U.S.C. § 355(b).

43. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman Act ("Hatch-Waxman"). Congress' principal intent was for Hatch-Waxman to reduce the regulatory hurdles faced by prospective generic manufacturers, allowing them to seek approval through an

expedited Abbreviated New Drug Application (“ANDA”) process in place of the lengthy and costly NDA approval process. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Under Hatch-Waxman, an ANDA applicant may rely on the safety and efficacy findings of the NDA for the referenced brand-name drug, if the ANDA demonstrates the proposed generic drug is both pharmaceutically equivalent (same dosage form, route of administration, identical strength, or concentration) and bioequivalent (no significant difference in the rate and extent of absorption of the active pharmaceutical ingredient). For ANDAs that pass this test, the FDA assigns an “AB” rating to the generic drug.

44. As a counterbalance to the relative ease with which generic manufacturers may obtain approval, Hatch-Waxman provided brand manufacturers with an opportunity to protect their intellectual property from generic infringement.

45. When the FDA approves a brand-name manufacturer’s NDA, it lists in a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as the “Orange Book”) any patents which, according to the information supplied to the FDA by the brand manufacturer: (1) claim the approved drug or its approved uses; and (2) for which a “claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1); (c)(2); (j)(7)(A)(iii).

46. The FDA’s role in maintaining the Orange Book is purely ministerial, and its listing of patents submitted to it in the Orange Book does not reflect the discretion or judgment of the agency.

47. To obtain FDA approval of an ANDA, the generic manufacturer must certify that it will infringe no patent listed in the Orange Book claiming the brand-name drug, because either:

- a. No patent for the brand-name drug has been filed with the FDA (a “Paragraph I Certification”);
- b. The patent for the brand-name drug has expired (a “Paragraph II Certification”);
- c. The patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a “Paragraph III Certification”); or
- d. The patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer’s proposed product (a “Paragraph IV Certification”).

21 U.S.C. § 355(j)(2)(A)(vii).

48. When a generic manufacturer files a Paragraph IV Certification, it must notify the brand manufacturer and patent owner, and Hatch-Waxman makes the ANDA filing itself an artificial act of patent infringement, entitling the patent holder to sue for injunctive relief.

49. If the patent holder sues the ANDA filer within 45 days of receiving a Paragraph IV Certification, Hatch-Waxman prevents the FDA from granting final approval to the ANDA until the earlier of (a) 30 months after the lawsuit is commenced, or (b) the court presiding over the patent infringement action rules that the patent is invalid or not infringed by the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). It is almost always the case that the 30 months expire before the court rules, resulting in a 30-month statutory stay.

50. However, during the 30-month stay, the FDA may grant “tentative approval” to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval, but for the 30-month stay. 21 C.F.R. § 314.3(b).

51. Hatch-Waxman grants a 180-day period of market exclusivity to the first Paragraph IV ANDA applicant that files a substantially complete ANDA. During the 180-day exclusivity period (measured from the first commercial marketing of the generic drug or the date of a court decision finding the listed patent invalid, unenforceable, or not infringed, 21 U.S.C. § 355(j)(5)(B)(iv)); *see also* 21 C.F.R. § 314.107(c)(1)), the first ANDA filer enjoys 180 days of freedom from competition from other generic versions of the drug, and during that period can capture almost all of the market for the drug by pricing slightly below the brand drug, but still selling the generic for higher prices than the market will support after additional generics enter the market.

52. The Supreme Court has recognized that “this 180-day period of exclusivity can prove valuable, possibly ‘worth several hundred million dollars’” to the first ANDA filer.⁴

53. The one exception to the first substantially complete ANDA filer’s “exclusivity” is that the brand manufacturer is free at any time, without engaging in another FDA approval process, to launch its own “authorized generic” (“AG”), or to license its AG to another manufacturer, as long as it does not bear the brand name on the product and is sold at a lower price than the branded product.

C. The Typical Sequence of Events Prior to Generic Entry.

54. Often, the first patent(s) filed by the brand drug manufacturer claiming a particular drug reflect(s) a bona fide medical achievement, innovating a new drug compound that provides the market with a previously unavailable therapy.

⁴ *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

55. But the brand manufacturer generally files additional patent applications as its research and development continues, relating to more specific formulations, processes for creating, and methods for using the original drug compound. These patents are only valid if the features and/or methods they claim are not obvious in light of, or anticipated by, previous patents, including the brand manufacturer's own original patents.

56. Part of a brand company's objective in filing applications for additional patents relating to the same drug is to extend the period of patent exclusivity.

57. The brand manufacturer's later patents, which often do not reflect a new, innovative drug compound, are more easily circumvented by would-be generic competitors. The generic manufacturers can simply design or invent around the later patents, or limit their own ANDA to uses of the drug compound not covered by the later patents.

58. Accordingly, the pharmaceutical market conditions and regulatory machinery lead generic manufacturers to aim to enter the market upon expiration of the initial patent or patents claiming the drug at issue, and not to wait until the expiration of all patents listed in the Orange Book.

59. An ANDA filer's Paragraph IV Certification—claiming that the brand manufacturer's patents are invalid or that the ANDA product will not infringe any valid patents—nearly always triggers a brand manufacturer's patent infringement lawsuit. As alleged above, simply filing suit within 45 days following receipt of a Paragraph IV Certification triggers a 30-month stay of ANDA approval, extending the brand manufacturer's monopoly period.

60. The statutory stay is automatic and not reflective of the merits of the brand manufacturer's patent infringement claims. Rather, in litigation, the brand manufacturer bears the burden of proving patent infringement.

61. The brand manufacturer's burden includes two components: (a) the validity of the asserted patents; and (b) the generic manufacturer's infringement of those patents.

62. A patent is invalid or unenforceable if, e.g., (a) the disclosed invention is anticipated or obvious in light of earlier prior art (including the brand manufacturer's own prior patents); (b) an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the United States Patent and Trademark Office ("USPTO"), fails to disclose material information known to that person to be material, or submits materially false information to the USPTO during prosecution; and/or (c) a later-acquired patent is not markedly distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

63. The USPTO's decision to issue a patent is not dispositive of any aspect of the brand manufacturer's patent infringement suit.

64. Indeed, Federal Trade Commission ("FTC") data show that generic challengers prevail in more than 70% of Hatch-Waxman patent infringement suits that are actually litigated to a decision on the merits.⁵

65. An ANDA filer with tentative approval that prevails on the merits of a Hatch-Waxman patent infringement suit may enter the market immediately. If the brand manufacturer prevails, the ANDA filer is barred from entering the market until the expiration of the ruled upon patents.

⁵ John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

66. Accordingly, any settlement of a Hatch-Waxman patent infringement suit reached in good faith and without collusive intent should reflect the parties' understanding of the probabilistic outcome of litigation to a decision on the merits. In other words, the stronger the brand manufacturer's position on the validity of the later patents and the generic's infringement of those patents, the later the agreed generic entry date should be. The weaker the brand manufacturer's position on either of those questions, the earlier the entry date.

67. Alongside Hatch-Waxman patent infringement litigation, brand manufacturers often file citizen petitions to erect another hurdle in the way of generic entry.

68. Citizen petitions are authorized under the FDCA as a mechanism for the public to express concerns about the safety or efficacy of a drug product. *See* 21 U.S.C. § 355(q); 21 C.F.R. § 10.31. In practice, brand manufacturers often use it to lodge baseless challenges to a generic product's bioequivalence, and the resolution of a citizen petition requires the FDA to expend significant public resources. The FDA often approves one or more ANDAs on the same day that it denies a brand manufacturer's citizen petition regarding those ANDAs.

69. Generally, the FDA prioritizes review of ANDAs for a first generic product, in order to enable the first substantially complete ANDA product to reach the market as soon as possible. As explained below, the FDA considers the introduction of more affordable generic alternatives to be a public health objective. As such, the FDA is mindful of key dates, such as the expiration of 30-month stays and 180-day exclusivity periods.

ECONOMIC BACKGROUND

70. AB-rated generic versions are therapeutically equivalent to their respective brand-name products. They are accordingly commodities differentiated from their brand competition by price only.

71. The first generic to enter a market may capture the majority of the market by pricing only slightly below the brand product.

72. Once multiple generic manufacturers enter the market, prices decrease rapidly, sometimes by as much as 90%.⁶ This is because competition among generic manufacturers forces the price to settle only slightly above the marginal cost of production.

73. The transition from one generic to multiple generics need not wait until the expiration of the first substantially complete ANDA filer's 180-day exclusivity period, although it often does. As alleged above, the brand manufacturer is free at any time to launch (or license) its own authorized generic product. Because AGs do not require FDA approval or any additional research and development, brand manufacturers are capable of producing them easily. Even as an AG drug competes with the brand drug, it also competes with ANDA generics, allowing the brand manufacturer to retain some of the market share it would otherwise lose to ANDA generics.

74. The FDA reported that in 2010, the use of FDA-approved generics saved consumers and payers \$158 billion, or \$3 billion per week, and that one year after entry, a generic drug takes over 90% of the corresponding brand-name drug's sales at 15% of the price. Generic drug entry, therefore, is a huge threat to the continued profitability of a brand drug.

75. Defendant Takeda Japan has acknowledged as much in its public filings, warning investors that "[t]he loss of market exclusivity for pharmaceutical products opens such products

⁶ See FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), available at <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> ("FTC Pay-for-Delay Study"); FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), available at <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf> ("FTC 2011 AG Study"); FTC Pay-for-Delay Study, at 1.

to competition from generic substitutes that are typically priced significantly lower than the original products, which typically adversely affects the market share and prices of the original products . . . The introduction of generic versions of a pharmaceutical product typically leads to a swift and substantial decline in the sales of the original product.”⁷

76. A prescription drug may be dispensed in the United States to a patient only by a licensed pharmacist pursuant to a doctor’s prescription which identifies the drug, and the prescription may be filled only with the brand name drug identified or an AB-rated generic version of the brand name drug. Pharmacists may (and, in most states, must) substitute an AB-rated generic for the brand-name drug, without seeking or obtaining permission from the prescribing doctor.

77. For every rung in the prescription drug ladder, there is a financial benefit to choose the generic drug. Pharmacies normally earn a higher markup on generic drugs because of pricing structure and federal reimbursement rules; private health insurers typically offer incentives to pharmacies to fill prescriptions with generics; and, to incentivize patients to request generic drugs, health insurers often offer lower copays for generic drugs than for brand-name drugs.

78. Since the passage of the Hatch-Waxman amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of

⁷ Takeda Pharmaceutical Company Limited, Annual Report (Form 20-F), at 9 (June 29, 2021), *available at* <https://www.sec.gov/ix?doc=/Archives/edgar/data/1395064/000139506421000140/tak-20210331.htm> (last accessed April 20, 2023).

pharmaceutical distribution and use facilitate both a rapid price decline and a rapid sales shift from the brand to the generic following the launch of an AB-rated generic.

D. Abuse of the Regulatory Structure.

79. Prior to 2003, if the first filer did not commercially market the generic drug and there was no court decision on the relevant Orange Book-listed patent(s), the commencement of the first filer's 180-day exclusivity period was delayed indefinitely, blocking final FDA approval of all subsequent ANDAs. This is colloquially referred to as "bottlenecking" or the "statutory block" of a subsequent ANDA.

80. To prevent this type of collusive behavior, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub. L. 108-173, 21 U.S.C. § 355(j)(5)(D)) (the "MMA"). The MMA creates numerous conditions under which a first filer forfeits its 180-day exclusivity, thereby allowing other ANDA filers to enter the market. For example, forfeiture occurs if the first filer fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements. 21 U.S.C. § 355(j)(5)(D)(i)(IV).

81. Under the "failure to market" provision, 21 U.S.C. § 355(j)(5)(D)(i)(I), a first filer forfeits its 180-day exclusivity if it fails to market its generic drug by the *later of*:

(a) *the earlier* of the date that is

(1) 75 days after receiving final FDA approval; or

(2) 30 months after the date it submitted its ANDA; or

(b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (i.e., as to each patent for which the first applicant

submitted a Paragraph IV certification), at least one of the following has occurred:

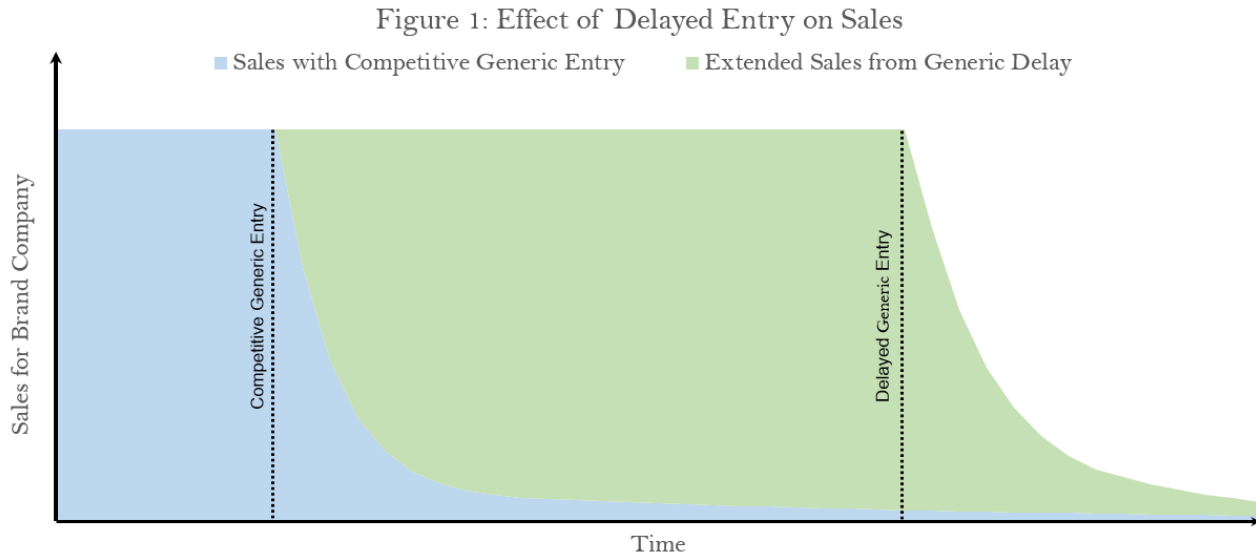
- (1) a final decision of invalidity or non-infringement;
- (2) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or
- (3) the NDA holder's delisting of the patent from the Orange Book.

82. However, the MMA did not succeed in preventing collusion between brand and generic drug manufacturers.

83. Brand manufacturers and first ANDA filers have occasionally chosen to use Hatch-Waxman patent infringement litigation as an opportunity for market allocation. In a reverse payment, or "pay-for-delay" settlement, the brand plaintiff pays the alleged infringing generic manufacturer to delay introduction of its ANDA product until an agreed date, often well past the date on which the conclusion of the relevant Hatch-Waxman patent infringement suit would greenlight the FDA's awarding of final approval to the first ANDA filer.

84. Brand and generic manufacturers structure their pay-for-delay settlements to circumvent the statutory forfeiture provisions and keep the 180-day exclusivity in place by, among other things, settling their litigation before a final judgment of invalidity or non-infringement can be entered, or by seeking a consent judgment that does not include a finding that all the patents for which the first filer submitted a Paragraph IV certification were invalid or not infringed. Consequently, a subsequent ANDA filer can fight this only by itself obtaining a judgment that all patents for which the first filer filed a Paragraph IV certification are invalid or not infringed, thereby triggering forfeiture of the first filer's 180-day exclusivity rights.

85. Pay-for-delay agreements allow brand and generic manufacturers to significantly forestall the onset of meaningful competition and consumer savings, and then to divide the supracompetitive profits that arise from both the brand manufacturer's prolonged monopoly and the two companies' subsequent 180-day duopoly. Not all Hatch-Waxman settlements are collusive. In a good faith settlement reflecting the parties' probabilistic expectations regarding



the outcome of their patent litigation, and absent a reverse payment from the brand manufacturer to the generic, the generic entry date is earlier. As Figure 1 shows, the pay-for-delay arrangement is immensely more profitable for both parties—and commensurately more expensive for consumers and payers—than a non-collusive settlement.

86. Competitive generic entry can also occur without settlement, if a generic manufacturer chooses to enter the market “at risk,” i.e. after the 30-month stay expires while the patent litigation remains pending.

87. When the brand and generic manufacturers opt for an unlawful pay-for-delay arrangement, the effect is to delay not only the first ANDA filer's entry but also the entry of any other generic manufacturers. As long as the agreement is crafted to avoid the forfeiture provisions

outlined above, the colluding generic company earns 180 days of exclusivity beginning only on its agreed entry date.

88. Later generic filers are also disincentivized from challenging the validity of the brand manufacturer's patents when they are forced to do so on their own, without any assistance from the colluding first ANDA filer. Later filers often cannot justify the costs of the litigation when they know their eventual market entry will have to be at a lower price than that available to the first ANDA filer.

89. In its landmark decision recognizing the anticompetitive nature of pay-for-delay settlements, the Supreme Court noted that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness" *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 158 (2013) ("*Actavis*").

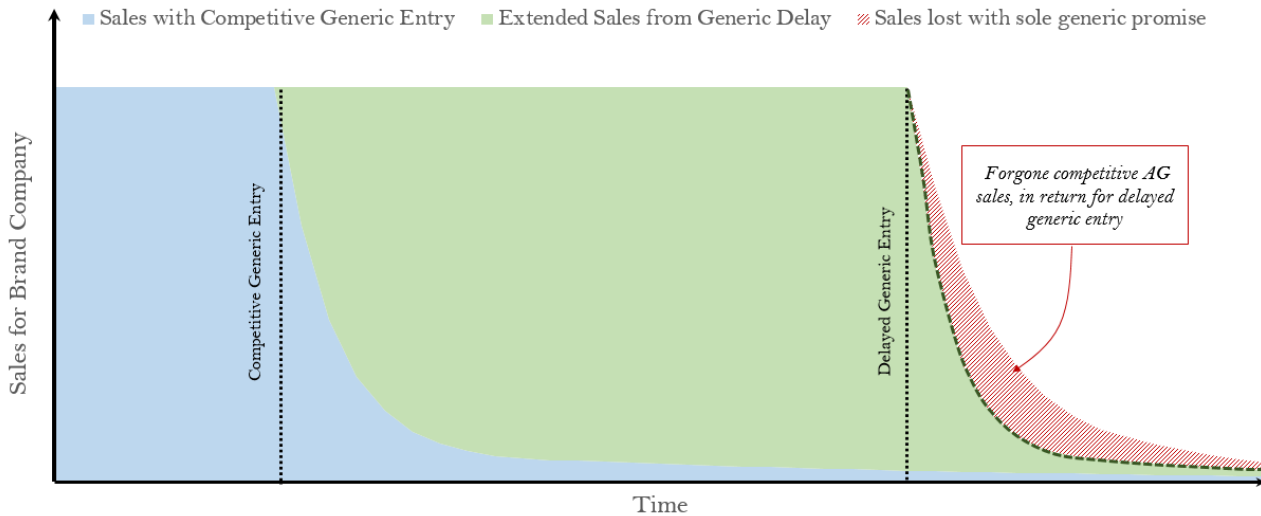
E. No-AG Agreements as an Alternative to a Cash Reverse Payment.

90. As a result of increasing regulatory scrutiny, congressional investigations, and class action lawsuits, brand and generic manufacturers have begun to structure more complex collusive agreements, disguising the brand manufacturer's reverse payment as something more innocuous.

91. One common form of disguised payment is a commitment by the brand manufacturer, in exchange for a delayed generic entry date, not to market or license an authorized generic to compete with the first ANDA filer for some period of time. As alleged above, the brand manufacturer is free to market an AG even during the first ANDA filer's 180-day "exclusivity." A commitment not to do so preserves the first ANDA filer's full control of the generic market and guarantees it a windfall.

92. As illustrated in Figure 2, in a so-called “no-AG” agreement, the brand manufacturer more than makes up for its loss of AG sale revenue by extending its monopoly period, and the generic manufacturer more than makes up for the foregone revenue of an earlier

Figure 2: Effect of Delayed Entry on Sales



entry date with a guaranteed six months of generic exclusivity. The losers of such an arrangement are other generic manufacturers, whose market entry is delayed, and consumers and payers, who have to pay monopoly and duopoly prices for years longer than they would have under competitive circumstances. As alleged above, the transition from a one-generic market to a multiple-generic market is usually accompanied by a significant price drop. No-AG agreements are designed to forestall that development.

93. In line with the economic reality, the FTC has taken the position that no-AG agreements are functionally equivalent to cash pay-for-delay agreements and potentially do even greater harm to competition in pharmaceutical markets:

Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, “if you go away for several years, I’ll give you

\$200 million.” Now, the brand might say to the generic, “if I launch an AG, you will be penalized \$200 million, so why don’t you go away for a few years and I won’t launch an AG.”⁸

94. Courts across the country, including in this District and the United States Court of Appeals for the First Circuit, recognize no-AG agreements as a form of actionable anticompetitive conduct under *Actavis*.⁹

95. However, increased scrutiny of the no-AG form of pay-for-delay agreement has driven brand-generic collusion to mutate further. Over time, the manufacturers began to structure their settlements to allow for an implicit, rather than explicit, no-AG guarantee.

96. For at least a decade, the FTC has observed that even patent settlements that do not contain an “explicit promise not to compete” may still “create[] incentives discouraging the brand from launching an AG that would compete against the first-filer.”¹⁰

97. One popular form of an implicit no-AG commitment is a so-called “declining royalty structure,” in which the first ANDA filer agrees to pay royalties to the brand manufacturer for some period of time following its market entry, but the percentage of royalties decreases if

⁸ FTC, *Statement of Chairman Jon Leibowitz on the Release of the Commission’s Interim Report on Authorized Generics* (June 24, 2009), available at <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf> (last accessed April 20, 2023).

⁹ *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 549 (1st Cir. 2016); *In re Opana ER Antitrust Litig.*, 162 F.Supp.3d 704, 719–20 (N.D. Ill. 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp’rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709–10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

¹⁰ FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (Aug. 2011), at 141, available at <https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission> (last accessed April 20, 2023).

the brand manufacturer markets its own competing AG. Although the brand manufacturer officially retains the right to introduce an AG, the agreement disincentivizes it from doing so. The implicit commitment not to market an AG compensates the first ANDA filer for its delayed entry date.

98. The FTC has recognized that declining royalty structure agreements “may achieve the same effect” as an explicit no-AG commitment,¹¹ and courts have found these agreements actionable under *Actavis*.¹²

DEFENDANTS’ CONDUCT

A. Sucampo’s Initial Development of Amitiza.

99. The therapeutic potential of prostaglandin E, a compound naturally occurring in the human body, was initially discovered by Japanese scientist Dr. Ryuiji Ueno. After several abortive patent applications in both Japan and the United States, Dr. Ueno obtained U.S. patent 5,166,174, directed to specific forms/compounds of prostaglandin E, in 1992, and U.S. patent 5,284,858 (“the ‘858 patent”), which claims prostaglandin E(1), the active pharmaceutical compound in Amitiza, in 1994.

100. Along with then-wife and research partner, Dr. Sachiko Kuno, Dr. Ueno founded R-Tech Ueno in Japan in 1989, and then founded Sucampo in 1996 for the purpose of commercializing his patents in the United States pharmaceutical market.

¹¹ FTC, *Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016* (May 2019), at 2, available at <https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-fy2016> (last accessed April 20, 2023).

¹² See *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 2021 WL 3612497, at *21 (N.D. Cal. Aug. 13, 2021) (collecting cases); *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639 (D. Mass. 2020).

101. Dr. Ueno's research process led to the development of lubiprostone, (RU-0211, or SPI-0211), a prostaglandin E1 metabolite analogue capable of alleviating constipation.

102. Constipation refers to the condition in which a person's bowel movements become difficult and infrequent, leading to pain and discomfort. Constipation can have multiple causes.

103. Lubiprostone is a locally acting chloride channel activator that promotes a chloride-rich intestinal fluid secretion without altering sodium and potassium concentration in the serum. Lubiprostone activates a chloride channel in the large intestine that causes the intestine to secrete chloride ions into the lumen (the central opening in the large intestine that waste passes through). Chloride ions are negatively charged, and so their presence draws positively charged sodium ions into the lumen. After that, the presence of both chloride ions and sodium ions draws water into the lumen (since a higher concentration of ions will attract more water, a process known as osmosis). By increasing intestinal fluid secretion, lubiprostone increases motility (movement) in the intestine and also softens the stool, thereby making the patient's defecation easier and more frequent.

104. All FDA-approved formulations of lubiprostone, including both Amitiza and generic versions, come in a capsule dosage form. Its efficacy is high, and the most common side effects are non-severe nausea and diarrhea.

105. To date, the FDA has approved lubiprostone for three indications:

- a. Chronic idiopathic constipation ("CIC") in adults (**approved January 31, 2006**):

Typically characterized by fewer than 3 bowel movements per week for 6 months or longer, without any known cause or identified underlying illness.

- b. Irritable bowel syndrome with constipation (“IBS-C”) in adult women (**approved April 28, 2008**): A chronic gastrointestinal disorder that causes frequent abdominal pain and bloating, accompanied by symptoms of constipation.
- c. Opioid-induced constipation (“OIC”) in patients with chronic, non-cancer pain (**approved April 22, 2013**): A common adverse effect experienced by patients receiving opioid drugs to treat chronic pain. (In August 2017, the FDA updated the label to add the language: “including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation”).

106. Sucampo submitted its first Investigational New Drug Application for lubiprostone to the FDA on December 29, 1999. After two 4-week randomized, placebo-controlled Phase III trials in patients with CIC (SC0131 and SC0232) showed that lubiprostone twice daily was statistically superior to placebo as measured by spontaneous bowel movement frequency rate during week 1, and additional safety studies, Sucampo began to prepare to seek FDA approval and begin commercialization. For these ends, Sucampo needed a more experienced partner.

B. Sucampo and Takeda’s Commercialization of Amitiza.

107. Takeda is a multinational pharmaceutical conglomerate headquartered in Japan that has been active in the United States market since 1977. Takeda’s experience and resources therefore made it a suitable partner for Sucampo, a younger Japanese entrant into the United States market.

108. Takeda and Sucampo signed an agreement on October 29, 2004 under which the companies would collaborate in the development, FDA approval, manufacture, and commercialization of lubiprostone (the “2004 Takeda-Sucampo Agreement”). The general

contours of the partnership left Sucampo responsible for clinical development, with Takeda responsible for commercialization, marketing, and sales.

109. Under the 2004 Takeda-Sucampo Agreement, Takeda received a 16-year license to co-develop, use, sell, promote, offer for sale, import, and distribute the product in the United States and Canada.

110. In October 2014, after the conclusion of the 2014 Takeda/Sucampo-Par Agreement addressed below, Takeda and Sucampo agreed to extend the terms of the 2004 Takeda-Sucampo Agreement beyond the end of 2020, after which time they would share evenly in revenue derived from brand Amitiza sales.

111. By the end of 2014, Sucampo had ceased all of its own direct Amitiza sales in the United States, leaving Takeda solely responsible for marketing and selling the drug here.

112. The 2004 Takeda-Sucampo Agreement also established formal steering, development, commercialization, and manufacturing committees to oversee the lubiprostone partnership. The steering committee included three executives from each side, met twice a year, kept minutes, and operated by unanimous decision-making. Unresolved issues would be elevated to the CEOs of Takeda and Sucampo.

113. The development committee, which oversaw clinical development and regulatory approval, included two representatives from each side, met quarterly, kept minutes, and operated by unanimous decision-making. However, the Agreement provided that all approval applications were to be filed in Sucampo's name.

114. Although, as of 2004, Sucampo had only begun to seek FDA approval for CIC treatment, the Agreement with Takeda provided that Takeda would earn up to \$50 million for each additional indication and would fund any required post-approval Phase IV studies.

115. The Agreement required Takeda to purchase the lubiprostone from Sucampo at a negotiated rate, and then pay royalties from its commercialization back to Sucampo. The precise royalty rate was set each year at one of six levels, ranging from 18-26%, based on annual net sales. Accordingly, at least 74% of Amitiza revenue was retained by Takeda.

116. Until 2015, Sucampo did not own any manufacturing facilities. Instead, the company contracted with R-Tech Ueno—in which Drs. Ueno and Kuno controlled a majority stake and which Sucampo publicly characterized as a “related party”—to manufacture Amitiza in order to meet Sucampo’s “commercial and clinical requirements.”¹³

117. Sucampo completed its acquisition of R-Tech Ueno and all of the latter’s outstanding shares on December 7, 2015, announcing, “We have now secured a larger portion of the global economics of AMITIZA® and greater control over the manufacturing and supply chain for the product.”¹⁴ Sucampo completed the acquisition through its wholly-owned Japanese subsidiary Sucampo Pharma LLC. Following the acquisition, R-Tech Ueno and its operations were fully integrated into Sucampo.

118. In the 2004 Takeda-Sucampo Agreement, Takeda and Sucampo committed to a collaborative maximization of patent protection for lubiprostone and its approved indications.

¹³ Sucampo Pharmaceuticals, Inc., Annual Report (Form 10-K/A), at F-30 (Mar. 16, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1365216/000117184316008620/f10ka_031616p.htm (last accessed April 20, 2023).

¹⁴ Press Release, Sucampo Pharmaceuticals, Inc., Sucampo Completes Acquisition of R-Tech Ueno (Dec. 7, 2015), *available at* <https://www.globenewswire.com/news-release/2015/12/07/793369/10116/en/Sucampo-Completes-Acquisition-of-R-Tech-Ueno.html> (last accessed April 20, 2023).

Takeda had to sign off on any patent prosecutions, patent strategy, and patent infringement lawsuits. Takeda was contractually guaranteed a say in patent litigation strategy, the right to join litigation as a party, and the right to commence a patent infringement litigation if Sucampo did not do so.

119. Takeda and Sucampo submitted their first lubiprostone capsule NDA, No. 21-908, in Sucampo's name, to the FDA on March 31, 2005. As alleged above, the FDA approved branded Amitiza for treating CIC in adults on January 31, 2006. Takeda began to sell the product in the United States in April 2006.

120. Although, upon initial approval of Amitiza, Sucampo submitted only four patents to the FDA for listing in the Orange Book, the partnership eventually submitted seventeen patents.

121. As alleged above, the '858 patent was Sucampo and Takeda's strongest. This patent, which expired on July 14, 2014 (following an extension to account for the duration of FDA review), claims the active pharmaceutical compound of Amitiza.

122. The other sixteen patents listed in the Orange Book had expiration dates between 2020 and 2027, and fall into three categories.

123. Seven patents claimed methods of use—including methods for which Amitiza has never received FDA approval. These patents are outlined in Figure 3 below.

FIGURE 3

Patent	Description	Issued (Expired)	Par's Position	Asserted Against Par?

7,064,148 ("the '148 patent")	U-1404 (001) U-739 (002)	06/02/2006 (08/30/2022)	CNS ¹⁵	No
8,748,481 ("the '481 patent")	U-1520 (001) U-1519 (002)	06/10/2014 (09/01/2025)	Issued After ANDA	No
6,982,283 ("the '283 patent")	U-1391 (001)	01/03/2006 (12/04/2022)	Unclear	No
7,795,312 ("the '312 patent")	U-1085 (002)	09/14/2010 (09/17/2024)	Paragraph IV	Yes
6,414,016 ("the '016 patent")	U-1392 (001) U-717 (001) U-874 (002)	07/02/2002 (09/05/2020)	Paragraph IV	Yes
8,071,613 ("the '613 patent")	U-1203 (001) U-1393 (001) U-1202 (002)	12/06/2011 (09/05/2020)	Paragraph IV	Yes
8,097,653 ("the '653 patent")	U-1214 (001) U-1394 (001)	01/17/2012 11/14/2022	Paragraph IV	Yes

124. Four patents claimed drug formulations. These patents are outlined in Figure 4 below.

FIGURE 4

Patent	Issued (Expired)	Par's Position	Asserted Against Par?
8,088,934 ("the '934 patent")	01/03/2012 (05/18/2021)	CNS	No

¹⁵ "CNS" stands for "covenant not to sue." As alleged below, a later-filing generic manufacturer alleged that Par received a covenant not to sue on these patents from Takeda and Sucampo.

6,583,174 ("the '174 patent")	06/24/2003 (10/16/2020)	CNS	No
7,417,067 ("the '067 patent")	08/26/2008 (10/16/2020)	CNS	No
8,097,649 ("the '649 patent")	01/17/2012 (10/16/2020)	CNS	No

125. Finally, five patents claim simple pharmaceutical formulations of prostaglandins.

These patents are outlined in Figure 5 below.

FIGURE 5

Patent	Issued (Expired)	Par's Position	Asserted Against Par?
8,114,890 ("the '890 patent")	02/14/2012 (09/05/2020)	CNS	No
8,779,187 ("the '187 patent")	07/15/2014 (01/23/2027)	Issued After ANDA	No
8,389,542 ("the '542 patent")	03/05/2013 (11/14/2022)	Paragraph IV	Yes
8,026,393 ("the '393 patent")	09/27/2011 (10/25/2027)	Paragraph IV	Yes
8,338,639 ("the '639 patent")	12/25/2012 (01/23/2027)	Paragraph IV	Yes

126. As alleged above, the FDA's listing of these sixteen additional patents in the Orange Book did not reflect any discretionary determination as to their strength. In fact, these patents—including even the seven that Sucampo and Takeda asserted against Par in Hatch-

Waxman infringement litigation¹⁶—were weak and posed no genuine impediment to generic entry into the lubiprostone market.

C. The Onset of Generic Activity.

127. In February 2010, after Amitiza had already enjoyed nearly four years of monopoly and two FDA-approved indications, Anchen filed ANDA 201442 to the FDA, seeking approval to manufacture, market, and sell a generic version of Amitiza in 8 and 24 mcg strengths as of the ‘858 drug substance patent’s July 14, 2014 expiration.

128. In August 2010, the FDA issued draft bioequivalence guidance for Amitiza generics (the “2010 Draft Guidance”), published information on how to conduct lubiprostone dissolution testing, and instructed Anchen to rerun its bioequivalence studies in line with the new guidance before the ANDA would be considered.

129. As with any draft or final guidance, the FDA’s decision to opine on Amitiza bioequivalence standards in August 2010 was meant to signal, and did signal, to the industry the FDA’s openness to considering and approving ANDA filings for generic entry into the lubiprostone market.

130. The 2010 Draft Guidance recommended two bioequivalence studies for ANDAs for orally administered lubiprostone capsules: (a) a comparative pharmacokinetic (“PK”) study of the 24 mcg dose in healthy males and females and (b) a comparative clinical endpoint study of the 24 mcg dose conducted in adults with CIC. These recommendations applied to all generic

¹⁶ According to the Amended Complaint filed by Sucampo, Sucampo GmbH, R-Tech Ueno, Takeda Japan, Takeda USA, and Takeda America, as of July 3, 2013, five of the seven patents asserted against Par and Anchen (‘016, ‘312, ‘613, ‘653, and ‘542) were owned by Sucampo GmbH, and the other two (‘393 and ‘639) were co-owned by Sucampo GmbH and R-Tech Ueno. As to all seven, however, Takeda Japan held an exclusive license. Takeda USA was a sublicensee of Takeda Japan, and Takeda America was a sublicensee of Takeda USA. *Sucampo AG v. Anchen Pharms., Inc.*, No. 13-202 (D. Del. Feb. 7, 2013), ECF No. 22 at ¶¶ 26-29.

formulations, regardless of how similar they were to the Amitiza formulation (e.g., regardless of whether they had qualitatively (Q1) and quantitatively (Q2) the same inactive ingredients as Amitiza).

131. The Guidance also recommended conducting dissolution testing on 12 dosage units, and referred to further product-specific dissolution testing information in the FDA's online Dissolution Methods Database, which was updated simultaneously with lubiprostone-specific methods.

132. The FDA indicated that in vivo bioequivalence testing of the 8 mcg dose could be waived based on (a) acceptable bioequivalence studies on the 24 mcg strength, (b) proportional similarity of the formulation across all strengths, and (c) acceptable in vitro dissolution testing on all strengths.

133. Armed with FDA feedback and a head start, Anchen continued to work quickly to prepare the first substantially complete ANDA for generic Amitiza. In January 2011, Anchen hired Novum Pharmaceutical Research to conduct the recommended bioequivalence studies for a total of \$6.4 million.

134. Anchen's Phase III three-arm (Amitiza, generic, placebo), double-blind randomized clinical study using the 24 mcg dose—as recommended by the FDA—kicked off in May 2011. 808 subjects enrolled.

135. As the study progressed, in November 2011, Par acquired Anchen, along with its ongoing lubiprostone development project. Par continued the bioequivalence studies and assumed all related outstanding debts.

136. Following completion of the Phase III study in June 2012, Par re-submitted Anchen's ANDA, and the FDA accepted it as substantially complete. Par now became the first ANDA filer, poised to win 180 days of generic exclusivity following the expiration of Sucampo and Takeda's '858 patent in July 2014.

137. Six months later, on December 26, 2012, Par sent a formal Paragraph IV Certification notice to Sucampo, informing Sucampo about its substantially complete ANDA and asserting that the twelve patents listed in the Orange Book as claiming Amitiza as of that date were invalid and/or would not be infringed upon Par's entry into the market in July 2014.

138. Sucampo represented that it received the notice on January 2, 2013, triggering the 45-day clock for filing a Hatch-Waxman patent infringement suit against Par and obtaining a 30-month stay.

139. Par sent Sucampo a supplementary Paragraph IV notice on January 24, 2013, in order to extend its invalidity/non infringement argument to the '639 patent, that had been issued on December 25, 2012, the day before Par sent its initial Paragraph IV Certification notice.

D. The Hatch-Waxman Action.

140. Sucampo and Takeda acted timely to obtain their 30-month stay of generic entry. On February 7, 2013, Takeda Japan, Takeda USA, Takeda America, Sucampo, Sucampo GmbH, and R-Tech Ueno sued Par, Par Pharmaceutical Companies, Inc., and Anchen (hereinafter collectively "Par") for patent infringement in the United States District Court for the District of Delaware. *See Sucampo AG v. Anchen Pharms., Inc.*, No. 13-202 (D. Del. Feb. 7, 2013), ECF No. 1. As outlined in Figures 3-5 above, Sucampo and Takeda asserted only seven patents against

Par: the ‘016, ‘312, ‘613, ‘653, ‘393, ‘639, and ‘542 patents.¹⁷ Under Hatch-Waxman rules, their suit set the earliest date for final approval of Par’s ANDA as July 2, 2015.

141. The litigation proceeded through discovery, with competing claim construction briefs filed on January 17, 2014. Takeda and Sucampo never asserted claims as to the remaining nine Orange Book-listed patents, seven of which were issued prior to Par’s ANDA.

142. On the same day they filed their claim construction brief, Takeda and Sucampo submitted a citizen petition to the FDA requesting that the FDA not approve generic Amitiza products without additional bioequivalence testing—beyond the standards endorsed in the 2010 Draft Guidance—allegedly meant to ensure that Amitiza generics demonstrated “the same safety profile” as the branded drug.

143. Takeda and Sucampo filed that citizen petition in the name of Sucampo Pharma Americas, LLC, a subsidiary of Sucampo.

144. As alleged above, the citizen petition mechanism is often abused by brand manufacturers seeking to delay generic entry and/or to exert pressure on generic manufacturers engaged in ongoing Hatch-Waxman patent infringement litigation. On information and belief, this same objective motivated the Takeda/Sucampo petition.

145. Takeda and Sucampo’s theory that the bioequivalence standards endorsed in the 2010 Draft Guidance were insufficient to ensure patient safety was supported not by evidence but by rank speculation:

¹⁷ The ‘542 patent issued on March 5, 2013, after litigation had commenced. Par sent Sucampo a third Paragraph IV Certification notice, asserting invalidity and/or non-infringement as to the ‘542 patent, on May 7, 2013, and Takeda and Sucampo amended their claim to include the ‘542 patent on July 3, 2013. No. 13-202, ECF No. 21 (D. Del.).

- a. “A generic lubiprostone product could demonstrate pharmacokinetic bioequivalence of a single-dose of 48 mcg, while having up to a 25% higher plasma concentration than AMITIZA. This higher effective dose *could* result in more adverse events.”¹⁸
- b. “[A] lubiprostone product that is more potent than AMITIZA *could* achieve efficacy endpoints but lead to diarrhea, and eventually, dehydration.”¹⁹

146. The FDA generally disfavors and regularly denies baseless and obstructive citizen petitions filed by brand manufacturers opposing generic entry.

147. Had Takeda and Sucampo truly believed their safety-based criticisms of the 2010 Draft Guidance had any merit, they could have participated in the public comment process following its publication four years earlier. Their failure to act until the six months before the expiration of the ‘858 compound patent and the potential entry of generic competition suggests an improper monopolistic motive.

E. The 2014 Takeda/Sucampo-Par Agreement.

148. In September 2014, Takeda, Sucampo, and Par used the opportunity of their ongoing patent litigation to craft a market allocation agreement that would delay generic entry and preserve their supracompetitive profits.

149. Under the 2014 Takeda/Sucampo-Par Agreement, (a) Par agreed to delay launching a generic version of Takeda’s Amitiza until January 1, 2021; (b) when Par eventually did launch, there would only be one generic in the market (either Par’s ANDA product alone or

¹⁸ Citizen Petition at II.B.3 (emphasis added), available at https://downloads.regulations.gov/FDA-2014-P-0144-0001/attachment_1.pdf (last accessed April 20, 2023).

¹⁹ *Id.* (emphasis added).

an authorized generic distributed by Par only), with both sides agreeing to split the generic revenue 50/50; and (c) Takeda/Sucampo agreed to prolong the one-generic only artifice by keeping other generics out of the market for as long as they possibly could.

150. On information and belief, the terms of the 2014 Takeda/Sucampo-Par Agreement were not fully reflected in the written settlement executed by the parties to terminate the patent infringement action. In fact, the written settlement helped conceal the true nature of the parties' Agreement by announcing the pretense that Sucampo and Takeda remained free to launch an authorized generic following Par's entry, when, in reality, the royalty structure was designed to disincentivize them from doing so.

151. The intended effect of the Agreement was to protect and extend Sucampo and Takeda's lubiprostone monopoly for six and half years beyond the expiration of the '858 patent, the only patent claiming the Amitiza therapeutic compound, and then to ensure that only one generic entered the market to compete with Amitiza for at least six months, and up to two years following the delayed entry date. Sucampo and Takeda traded away their ability to launch an AG to compete with the first ANDA filer in exchange for additional years of monopoly pricing, and Par traded away its timely entry into the market in exchange for a profitable period of generic exclusivity.

152. Sucampo's effective commitment not to launch an AG constituted an unlawful reverse payment to Par, the alleged infringer of its Amitiza patents.

153. Although Sucampo was nominally the party receiving AG royalties, Takeda participated in the Agreement and shared heavily in its benefits. As alleged above, Takeda held exclusive licenses to all seven patents asserted against Par, joined the patent infringement action as a plaintiff, and signed the 2014 Takeda/Sucampo-Par Agreement. Under its 2004 Agreement

with Sucampo, Takeda committed to participate aggressively in the protection of Sucampo's Amitiza patents.

154. Takeda reaped the benefits of the pay-for-delay arrangement, in the form of extra years of monopoly pricing. Indeed, the royalties paid by Par to Sucampo were not themselves the primary asset that Takeda and Sucampo purchased with their effective reverse payment. Rather, the two brand partners were primarily concerned with delaying the onset of generic competition. The royalties functioned as a mechanism to disincentivize Sucampo's introduction of its own additional AG.

155. Through its claim on 74% of Amitiza sales revenue, Takeda benefitted directly from the exclusion of generic competition until January 2021.

156. Underlying this effective no-AG commitment was the sort of "declining royalty" structure that the FTC has recognized to be functionally equivalent to an explicit no-AG guarantee, as explained above.

157. Specifically, the Agreement allowed Par to enter the market as of January 1, 2021, either with its own ANDA generic product, or with an AG licensed to it by Sucampo. For at least six months—i.e., the statutorily guaranteed 180-day generic exclusivity period—the two sides would split the generic profits 50/50. After one generic would enter the market, Sucampo's share of Par's generic royalties would decline to 15%. After multiple generics would enter, Sucampo would receive no royalty.

158. The declining royalty structure ensured that, regardless of Sucampo's reservation of the right to launch an AG, it was heavily incentivized not to do so. As alleged above, generic prices tend to drop significantly upon entry of the second generic product. Thus, Sucampo stood to gain much more by receiving 50% of the royalties from the only generic on the market, than it

could have gained by taking 15% of Par's generic and launching its own AG, thereby causing prices to plummet for everyone.

159. The same declining royalty percentages applied regardless of whether Par would choose to pursue its own ANDA product or launch an AG licensed to it by Sucampo.

160. Sucampo, Takeda, and Par also all stood to gain from forestalling other generic competition for as long as possible, preserving their duopolistic pricing conditions. Sucampo and Takeda had the power to do this by aggressively litigating patent infringement claims against all subsequent ANDA filers.

161. Absent collusion, the brand company and the first ANDA filer would be competitors, incentivizing the brand company to launch its own AG (or license it to a third party) in order to preserve some of its market share and recoup its losses. Indeed, as shown in Figure 6 below, on at least four occasions, Takeda has done just this for its own drugs:

FIGURE 6

Takeda Drug Name	Date of authorized generic entry	Third party marketing and selling the authorized generic
Duetact (pioglitazone and glimepride)	Aug. 4, 2015	Prasco
Kazano (alogliptin and metformin)	Apr. 2016	Perrigo
Nesina (alogliptin)	Apr. 2016	Perrigo
Oseni (alogliptin and pioglitazone)	Apr. 2016	Perrigo

162. The industry standard in a competitive market has the AG licensee pay the brand company 90% of the royalties. Sucampo and Takeda's agreement to accept a ceiling of 50% was another component of their reverse payment to alleged infringer Par.

F. The Value of 180 Days of Generic Exclusivity to Both Sides of the Agreement.

163. Each year, U.S. purchasers spend hundreds of millions of dollars on Amitiza. According to IQVIA, Amitiza U.S. sales were about \$427 million for the 12 months ending on Sept. 30, 2020. Premera uses this figure to estimate the value of the 180 days of generic exclusivity guaranteed by the 2014 Takeda/Sucampo-Par Agreement.

164. Absent the anticompetitive Agreement, and using industry standards, if Par launched its ANDA product, and Sucampo/Takeda launched an AG, the two generics would be priced at approximately 60% of the brand, would together take 90% of all lubiprostone unit sales, and Par would make half of the generic sales. Par's revenues during the first 180 days (when other ANDA generics are foreclosed from the market by FDA regulation) would be $(\$427 \text{ million}) * (0.5 \text{ year}) * (0.6 \text{ percentage of the brand price}) * (0.9 \text{ generic penetration}) * (0.5 \text{ of the generic market}) = \57.6 million . And Takeda/Sucampo would make the same amount if they launched an AG, \$57.6 million.

165. Under the Agreement, however, both sides stood to do much better. Par was allowed to launch a generic—either its own ANDA product or an AG—free from competition by a Sucampo/Takeda AG. Using industry standards, Par's generic would be priced at about 90% of the brand, and would take 90% of all lubiprostone unit sales, and 100% of all generic sales. Par's revenues during the first 180 days would be $(\$427 \text{ million}) * (0.5 \text{ year}) * (0.9 \text{ percentage of the brand price}) * (0.9 \text{ generic penetration}) * (1 \text{ sole entrant in the generic market}) = \173 million . Par would pay a 50% royalty to the brand and retain the other 50% = \$86.5 million.

166. The \$28.9 million difference between Par's expected revenue in a competitive market and its revenue under the Agreement was the reverse payment Par received from Sucampo and Takeda in exchange for delaying its entry into the market. \$28.9 million far exceeds any reasonable estimate of the litigation expenses that Takeda and Sucampo saved by settling their patent infringement action.

167. Using the same figures, it is easy to see how the declining royalty structure made it economically irrational for Sucampo to launch a competing AG during Par's period of generic exclusivity. Takeda's revenues for an AG during that time would be $(\$427 \text{ million}) * (0.5 \text{ year}) * (0.6 \text{ percentage of the brand price}) * (0.9 \text{ generic penetration}) * (0.5 \text{ of the generic market}) * (1.15 \text{ full AG profit plus } 15\% \text{ royalty from Par}) = \66.3 million , far less than the \$86.5 million that Takeda received under the terms of the 2014 Takeda/Sucampo-Par Agreement.

168. The Agreement also sought to extend the generic exclusivity period beyond 180 days, to as long as 2 years. This potential promised massive supracompetitive profits for both sides.

169. Assuming roughly constant Amitiza sales and 90% generic penetration at 90% of the brand price, Par's estimated revenues over that two-year period would be $(\$427 \text{ million}) * (2 \text{ years}) * (0.9 \text{ generic penetration}) * (0.9 \text{ percentage of the brand price}) = \692 million . After paying a 50% royalty, Par would retain about \$346 million.

170. Absent collusion, Par and Sucampo/Takeda would each have earned \$57.6 million in the first 180 days of generic entry, as explained above. After the first 180 days, there would have been at least a Sucampo/Takeda AG and a Par ANDA generic, and possibly other ANDA generics all sharing the 90% generic share of the market at a lower price. If the Sucampo/Takeda AG and the Par ANDA generic were the only generics on the market, they would each earn $(\$427$

million) * (1.5 years) * (0.9 generic penetration) * (0.6 percentage of the brand price) * (0.5 each generic's share of the market) = \$173 million over that period. Par and Sucampo/Takeda's total generic revenues for that two-year period would have been only (\$57.6 million) + (\$173 million) = \$231 million each. With additional generic entrants after the 180-day period, the generic price would have been even lower and the generic market split more ways, and both sides' revenues would have been much lower.

171. The value of two years of generic exclusivity to Par is the difference between the revenue that it will receive during the two years after paying a 50% royalty (\$346 million) and what it would have received absent any anticompetitive agreements (at most \$231 million), which is at least \$115 million. Sucampo, as well, locked in \$346 million during the two years, when it would have received no more than \$231 million during that same time period absent collusion.

172. The value of these unlawful reverse payments far exceed what Par would have earned had it prevailed in the patent litigation, and these payments induced Par to accept a delay of its generic entry until January 2021 and drop its challenge to the vulnerable Amitiza patents.

173. The guaranteed 180 days of generic exclusivity were valuable to Par for another reason: They enabled Par to stop pursuing FDA approval of its ANDA product. In the absence of the Agreement, Par would have had to continue expending resources to seek approval within thirty months of filing its ANDA or else risk forfeiting its right to 180 days of generic exclusivity. The Agreement gave Par the same exclusivity—or even more, up to two years' worth—without any need to continue the complex and costly ANDA process. Thus, although Par's ANDA was on track for FDA approval, Par was gifted an easier and cheaper route to the same objective in exchange for delaying initial generic entry.

174. As soon as the 2014 Takeda/Sucampo-Par Agreement was announced, the stock market understood its significance for Sucampo's—and by contractual implication, Takeda's²⁰—profits. After Sucampo announced the settlement in a Form 8-K after the close of business on October 9, 2014, its stock price increased by an adjusted return of +11.5% on October 10.²¹

G. Takeda, Sucampo, and Par's Concealment of the Anticompetitive Nature of their Agreement.

175. The success of Takeda and its co-conspirators' anticompetitive pay-for-delay scheme depended upon their ability to evade the scrutiny of regulators, payers, and the public. Reframing the 2014 Takeda/Sucampo-Par Agreement as a legitimate litigation settlement with procompetitive benefits therefore become a crucial component of Takeda, Sucampo, and Par's conspiracy.

176. They began the public relations effort within two weeks of signing the Agreement. In the aforementioned Sucampo press release/Form 8-K filing on October 9, 2014, Sucampo announced that the Agreement granted Par:

a non-exclusive license to market Par's generic version of lubiprostone 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule (licensed products) in the U.S. for the indications approved for AMITIZA beginning January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par will split with Sucampo the gross profits of the licensed products sold during the term of the agreement, which continues

²⁰ Takeda's ADRs did not begin to trade in U.S. public markets until 2018.

²¹ Thomas McGuire et al., *Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements*, 101 IOWA L. REV. 1581 (2016), Harvard Pub. L. Working Paper No. 16-18, available at SSRN: <https://ssrn.com/abstract=2593944> (“An otherwise unexplained bump in the patent holder's stock price shows that the settlement created new future profits by extending the period without generic competition beyond what the stock market expected.”) (last accessed April 20, 2023).

until each of the Sucampo patents has expired. In the event Par elects to launch an authorized generic, Sucampo will supply Par under the terms of a manufacturing and supply agreement at a negotiated price. Additional details of the agreement remain confidential.²²

177. This summary contained numerous mischaracterizations that served the parties' objective of concealment. First, the supposed "non-exclusiv[ity]" of Par's AG license was a fiction. As explained above, the declining royalty structure was designed to disincentivize Sucampo's introduction of a competing AG product, thereby ensuring Par's exclusivity.

178. Second, the assertion that Par and Takeda/Sucampo agreed to "split" the gross profits suggests a stable division, concealing the fact that Takeda/Sucampo's share of the profits would decline upon the emergence of any real competition in the generic Amitiza market.

179. Third, the summary conveys the impression that it contains all the details material to regulators and the public, while only mere "[a]dditional materials" would "remain confidential." In reality, the confidential declining royalty structure details were the most important terms of the Agreement, facilitating Takeda and Sucampo's large reverse payment to Par in exchange for delayed generic entry.

180. The public relations effort continued on November 7, 2014, when Sucampo attached a redacted version of the September 30, 2014 written settlement agreement to its quarterly S.E.C. filing.²³ This filing redacted, among other terms, the royalty rates owed by Par

²² Sucampo Pharmaceuticals, Inc., Form 8-K, at Ex. 99.1 (Oct. 9, 2014) (emphasis added), *available at* <https://www.sec.gov/Archives/edgar/data/1365216/000117184314004692/newsrelease.htm> (last accessed April 20, 2023).

²³ Sucampo Pharmaceuticals, Inc., Quarterly Report (Form 10-Q), at Ex. 10.2 (Nov. 7, 2014), *available at* https://www.sec.gov/Archives/edgar/data/1365216/000117184314005351/f10q_110614.htm (last accessed April 20, 2023).

to Sucampo upon its entry into the market, upon the entry of one additional generic product, and upon entry of two or more additional generic products, i.e. the substance of the declining royalty structure, the most important anticompetitive feature of the Agreement.

181. At the same time, Sucampo's filing pointedly did not redact the provision expressly reserving the right to launch or license an additional AG to compete with Par's generic. This was an essential misdirection because, as explained above, the purpose of the declining royalty structure was to prevent Sucampo from doing exactly that.

182. Finally, on November 21, 2014, the parties to the ongoing Hatch-Waxman patent infringement litigation (including all Defendants here) filed a proposed consent judgment for the district court's approval. The proposed judgment misleadingly represented that the Agreement would have "procompetitive" value inuring "to the benefit of the parties and consumers alike." *Sucampo AG v. Anchen Pharms., Inc.*, No. 13-202 (D. Del.), ECF No. 119-1 at 2. The court so-ordered the consent judgment on December 2, 2014. *Id.* at ECF No. 121.

H. The Anticompetitive Impact of the 2014 Takeda/Sucampo-Par Agreement.

183. On July 17, 2015, the FDA denied Takeda and Sucampo's January 17, 2014 citizen petition challenging the lubiprostone bioequivalence standards endorsed in the 2010 Draft Guidance. The FDA emphasized that the notion that the generic product could have a "different safety profile from Amitiza is speculative and *not supported by any scientific basis.*"

184. As alleged above, the FDA regularly approves one or more ANDAs on the same day that it denies a brand manufacturer's citizen petition regarding those ANDAs. This timeline makes clear that Par, the unambiguous target of Sucampo and Takeda's baseless citizen petition, was on track for FDA approval, and would have obtained such approval if the 2014 Takeda/Sucampo-Par Agreement had not eliminated its motivation to do so.

185. Had Par obtained FDA approval by July 2015, it would have made economic sense for it to launch its generic lubiprostone product “at risk” following expiration of the 30-month stay and regardless of the status of the patent infringement action. In similar circumstances, a generic almost always launches at risk.²⁴ Par itself had launched at risk at least four times before, including at least twice launching before a district court decision on the merits.

186. A competitively acting company in Takeda’s position would have launched an AG to compete with Par. In similar circumstances, a brand almost always launches an AG when the first generic comes to market.

187. Most importantly for consumers and payers, in the absence of the 2014 Takeda/Sucampo-Par Agreement, additional generic products would have been available sooner, lowering prices across the market.

188. What transpired in the lubiprostone market was much more bleak. Pursuant to the terms of the Agreement, Par waited to introduce a generic until 2021, finally launching its Sucampo-licensed AG on January 4, 2021.

189. To date, the FDA has approved ANDAs for generic lubiprostone products filed by four additional generic manufacturers: Amneal Pharmaceuticals LLC (November 30, 2021), Teva Pharmaceuticals USA Inc. (January 18, 2022), Dr. Reddy’s Laboratories Ltd. (February 8, 2022), and Zydus Pharmaceuticals (USA) Inc. (March 23, 2023).

190. Takeda and Sucampo have pursued and resolved patent infringement claims against each of these manufacturers:

²⁴ See, e.g., Keith M. Drake et al., *No Free Launch: At-Risk Entry by Generic Drug Firms*, NBER Working Paper 29131 (Aug. 2021), available at <http://www.nber.org/papers/w29131> (last accessed April 20, 2023).

- a. **Dr. Reddy's Litigation:** On November 12, 2014, Sucampo, Sucampo GmbH, R-Tech Ueno, Takeda Japan, Takeda USA, and Takeda America sued Dr. Reddy's Laboratories Ltd. for infringement of the same seven patents underlying the Par litigation. *Sucampo AG et al. v. Dr. Reddy's Laboratories, Inc. et al.*, No. 3:14-cv-07114, ECF No. 1 (D.N.J.). The parties' consent judgment, ordered on November 21, 2016, stipulates to a January 1, 2023 entry date without any reverse payment to Dr. Reddy's. *Id.* at ECF No. 67.

- b. **Amneal Litigation:** On April 13, 2017, Sucampo, Sucampo GmbH, Sucampo Pharma LLC, Takeda Japan, Takeda USA, and Takeda America sued Amneal Pharmaceuticals LLC for infringement of the '653 patent, the '542 patent, the '393 patent, and the '639 patent (four of the seven asserted against Par), and the '283 patent (not asserted against Par). *Sucampo Pharma LLC et al. v. Amneal Pharmaceuticals LLC*, No. 3:17-cv-02577, ECF No. 1 (D.N.J.). The parties' consent judgment, ordered on September 19, 2018, stipulates to a January 1, 2023 entry date without any reverse payment to Amneal. *Id.* at ECF No. 46.

- c. **Teva Litigation:** On September 25, 2017, Sucampo, Sucampo GmbH, Sucampo Pharma LLC, Takeda Japan, Takeda USA, and Takeda America sued Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. for infringement of the same seven patents underlying the Par litigation, as well as the '283 patent and the '481 patent. *Sucampo AG et al. v. Teva Pharmaceutical Industries Ltd. et al.*, No. 3:17-cv-07451, ECF No. 1 (D.N.J.). The parties' consent judgment, ordered on September 19, 2018 (the same day as the Amneal judgment),

stipulates to a January 1, 2023 entry date without any reverse payment to Teva.

Id. at ECF No. 31.

- d. **Zydus Litigation:** On January 28, 2020, Sucampo, Sucampo GmbH, Sucampo Pharma LLC, Sucampo Pharma Americas LLC, Takeda Japan, Takeda USA, and Takeda America sued Zydus Pharmaceuticals (USA) Inc. for infringement of the ‘312 patent, the ‘393 patent, and the ‘639 patent (three of the seven asserted against Par), and the ‘187 and ‘481 patents (not asserted against Par). *Sucampo GmbH et al. v. Zydus Pharmaceuticals (USA) Inc.*, No. 3:20-cv-00936, ECF No. 1 (D.N.J.). The parties’ consent judgment, ordered on November 13, 2020, stipulates to a January 1, 2023 entry date without any reverse payment to Zydus. *Id.* at ECF No. 16.

191. At least one additional generic manufacturer has filed a still-pending ANDA for generic lubiprostone, triggering patent infringement claims by Takeda and Sucampo:

- a. **Sun Litigation:** On October 30, 2018, Sucampo, Sucampo GmbH, Sucampo Pharma LLC, Takeda Japan, Takeda USA, and Takeda America sued Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. for infringement of the ‘312 patent, the ‘653 patent, the ‘542 patent, the ‘393 patent, and the ‘639 patent (five of the seven asserted against Par), and the ‘187 and ‘481 patents (not asserted against Par). *Sucampo AG et al. v. Sun Pharmaceutical Industries, Ltd. et al.*, No. 3:18-cv-15482, ECF No. 1 (D.N.J.). The parties’ consent judgment, ordered on July 1, 2020, stipulates to a January 1, 2023 entry date without any reverse payment to Sun. *Id.* at ECF No. 34.

192. The clear pattern that emerges from Takeda and Sucampo's protection of their Amitiza patents demonstrates that they acted with the goal of preserving two full years of duopoly pricing, the profits of which they share with Par.

I. Takeda and Sucampo's Weak Patents Never Posed a Real Obstacle.

193. The argument that Par's contemplated ANDA generic product would not have infringed any valid patents following expiration of the '858 patent was articulated by Par itself in its Paragraph IV Certification notices. While these notification letters are not publicly available, their existence is not in doubt, and their contents will provide compelling evidence that the 2014 Takeda/Sucampo-Par Agreement provided for a delayed generic entry.

194. This argument is even stronger as to the nine Orange Book-listed Amitiza patents that Takeda and Sucampo never asserted against Par, reflecting their acknowledgment of the patents' weakness and/or irrelevance to Par's ANDA product. Of these nine, six (the '934, '174, '067, '649, '148, and '890 patents) were never asserted against any Amitiza ANDA filer.

195. As alleged above, none of the seven Amitiza patents asserted against Par claimed the Amitiza therapeutic compound. Four claimed methods of treating various diseases by administering certain drug products and three claimed simple formulations of prostaglandins.

196. Method of use patents, like all patents, must claim novel and non-obvious improvements over the prior art to be upheld in court. 35 U.S.C. §§ 102-03. All four method of use patents asserted against Par claimed methods of using the prostaglandin compounds to treat constipation and/or irritable bowel syndrome. The use of prostaglandin compounds to treat constipation and irritable bowel syndrome was well known in the art at least as early as 1987, many years prior to the earliest filed of the method of treatment patents asserted against Par. Accordingly, all the methods of use patents would have been found invalid, unenforceable,

and/or not infringed by the manufacture, use or sale of the generics' ANDA products, and therefore would not have impeded Par's market entry for generic Amitiza beyond the 30-month stay.

197. The three formulation patents would likewise have been held invalid, unenforceable, and/or not infringed by the manufacture, use or sale of the Par's ANDA products. Each of them claims formulations of prostaglandin compounds, using known excipients to formulate a pharmaceutical dosage form (at least two of which are gel cap formulations). For example, the gel cap has been known in the art for nearly 200 years; none of the claims would have met the standard of non-obviousness to prevent Par's market entry for generic Amitiza absent the 30-month stay.

MARKET POWER ALLEGATIONS

A. Third-Party Payers and Pharmaceutical Choice.

198. TPPs like Premera pay for pharmaceutical products for their members, but do not choose these products. State laws prohibit pharmacies from dispensing drugs like Amitiza to patients without a prescription. The prescribing physician therefore chooses the product, and the patient's TPP pays for it.

199. TPPs, including Premera, ordinarily utilize formularies to steer their members to more cost-effective treatment options. For instance, if a patient's physician prescribes brand drug X, and an AB-rated generic of X is available, the patient's TPP will incentivize the patient to opt for the generic by assigning a higher cost-sharing obligation to the brand drug. This cost-sharing obligation usually takes the form of a copay.

200. In this hypothetical, the TPP will pay for either brand X or generic X for the patient, leaving the choice up to the patient. But because brand X costs the TPP more than

generic X, and because the FDA has found the two options to possess equal therapeutic value, the TPP will charge the patient a higher copay for brand X than for generic X.

201. The systemic outcome of the formulary incentive system, utilized by Government healthcare programs and private TPPs alike, prevents unnecessary inflation of insurance premiums and facilitates a shift in market share from expensive brand drugs to less expensive generic ones. This results in greater access to low-cost generic drugs and less strain on taxpayer-funded Government healthcare programs.

202. Of course, the formulary incentive system cannot function as intended when pharmaceutical companies collude to prevent or delay generic entry.

203. When the market for a particular pharmaceutical product is controlled entirely by the brand drug, payers cannot be sensitive to price. Because bioequivalent products are unavailable, rising prices cannot drive payers to substitute another product.

204. When the market for a particular pharmaceutical product is occupied by a brand drug and one AB-rated generic, payers can be more sensitive to price, but, as alleged above, the generic can price just slightly below the brand price and capture 90% of the market. Payers' price sensitivity ends at the exclusive generic's price point.

205. When the market for a particular pharmaceutical product includes multiple generic alternatives, they will compete for share of payers by lowering their prices down to near the marginal cost of production.

206. The ability to profitably raise prices substantially above the marginal cost of production is known as "market power."

207. The extent to which rising prices of a product cause unit sales to decline because of substitution to other products is known as “cross-price elasticity of demand.”

208. Brand-only markets are inelastic, markets with one generic are mildly elastic, and markets with multiple generics are relatively highly elastic.

B. The Lubiprostone Market.

209. To the extent Premera must define a relevant market to prove market power, Premera alleges that the relevant product market is for Amitiza and its AB-rated generic alternatives (“the Lubiprostone Market”).

210. The relevant geographic market is the United States, the District of Columbia, and the U.S. territories.

211. Until July 14, 2014, the Takeda-Sucampo partnership had lawful monopoly power in the relevant market protected by the ‘858 patent claiming the therapeutic compound.

212. Between July 14, 2014 (or at least as early as July 17, 2015, the date on which the FDA denied Sucampo’s citizen petition) and January 1, 2021, the Takeda-Sucampo partnership had unlawful monopoly power in the relevant market, purchased from Par with the reverse payment described above.

213. Between January 1, 2021 and January 1, 2023, the market was controlled by Takeda/Sucampo’s Amitiza and Par’s AG product. This may be characterized as either a duopoly, or as a monopoly controlled by a tripartite partnership between Sucampo, Takeda, and Par. Sucampo and Takeda share the profits of Amitiza, and Sucampo and Par share the AG profits.

214. Until January 1, 2023, Takeda and Par possessed the power to exclude competition in the relevant market and to raise the prices of lubiprostone products to supra-competitive levels without losing enough sales to make such prices unprofitable.

215. Takeda and Par did not need to control the market for any other products in order to profitably maintain supracompetitive lubiprostone prices. Because Amitiza and its AG are substitutable only with AB-rated generics, and no other generics were available on the market, Takeda and Par's price increases would not cause them to lose unit sales.

216. The prices charged by Takeda and Sucampo prior to January 4, 2021, and by Takeda, Sucampo, and Par from January 4, 2021 until the date when the anticompetitive effects of their conduct ceased, were well in excess of the marginal cost of production.

217. Premera also does not need to define the relevant product and geographic markets, because there exists direct evidence of Takeda and Par's market power and its anticompetitive effects. The direct evidence includes, *inter alia*, (a) that a first generic Amitiza would have entered the market at a much earlier date if not for Takeda, Sucampo, and Par's anticompetitive conduct; (b) multiple subsequent generic Amitiza products would have entered the market at a much earlier date if not for Takeda, Sucampo, and Par's anticompetitive conduct; and (c) Takeda and Par's gross margins on Amitiza and AG Amitiza were very high.

C. The Anticompetitive Effects of the 2014 Takeda/Sucampo-Par Agreement.

218. Takeda and Par's pay-for-delay agreement had the purpose and effect of restraining the United States market for lubiprostone. Discerning the anticompetitive nature of the agreement requires no speculation; on at least two occasions, the FTC has determined that Par conspired to restrain and did restrain pharmaceutical markets by way of the same pay-for-delay mechanism.

219. First, on January 27, 2009, the FTC filed suit in the Central District of California alleging that brand manufacturer Solvay Pharmaceuticals, Inc. paid generic manufacturers Par and Watson Pharmaceuticals, Inc. to delay entry of generic competition for Solvay's testosterone replacement drug AndroGel. *Fed. Trade Comm'n v. Watson Pharm., Inc. et al.*, No. CV-09-00598 (C.D. Cal.). This action, along with private suits consolidated with it, led to the Supreme Court's monumental *Actavis* ruling in 2013. The FTC's claims against Par were resolved in a February 2, 2017 settlement with Par's parent Endo International plc.

220. Second, on August 18, 2015, Par and Concordia Pharmaceuticals Inc. settled FTC charges that Concordia agreed not to release an authorized AG version of its Attention Deficit Hyperactivity Disorder drug Kapvay to compete with Par's generic Kapvay, in exchange for a share of Par's revenues. *See In re Concordia Pharmaceuticals Inc. et al.* (F.T.C. File No. 151-0030).

221. Even putting aside Par's prior tradecraft, however, the circumstances of the 2014 Takeda/Sucampo-Par Agreement leave little doubt as to its anticompetitive nature. As alleged above, none of the Sucampo patents asserted against Par posed any real obstacle to generic entry, and Par was free to enter the market at risk. In the absence of the Takeda/Sucampo-Par Agreement, Par would have entered the market earlier, and additional generics would have followed upon the earlier expiration of Par's 180-day exclusivity.

222. Because generic competition provides consumers and payers access to lower-priced pharmaceuticals, Takeda, Sucampo, and Par's conspiracy caused Premera and members of the Class to pay more for lubiprostone than they would have in a competitive market.

223. Absent Takeda, Sucampo, and Par's unlawful conduct, Premera and the Class would have substituted generic Amitiza for brand Amitiza earlier, and would have paid less for

generic Amitiza as a result of multiple-generic competition. Even brand Amitiza itself would have been priced at a lower level as a result of generic competition.

224. Thus, Takeda, Sucampo, and Par deprived Premera and members of the Class of the benefits of competition that the antitrust and consumer protection laws are designed to ensure.

225. As a consequence, Premera and other members of the class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

CONTINUING VIOLATIONS AND FRAUDULENT CONCEALMENT

226. Premera alleges a continuous course of wrongdoing that includes actions taken within the relevant limitations periods.

227. Premera's causes of action accrued each time Takeda and Par sold Premera brand or AG Amitiza at a supracompetitive price made possible by Takeda, Sucampo and Par's unlawful scheme. Each sale at a supracompetitive price constituted an overt act in furtherance of the conspiracy.

228. Par's forbearance from entering the market until January 2021 constituted another overt act in furtherance of the conspiracy.

229. Premera is also entitled to recover damages reaching beyond the relevant limitations periods, as measured from the date of filing this action, as a result of Takeda's fraudulent concealment of its unlawful conduct.

230. As alleged above, the conspirators affirmatively concealed the anticompetitive nature and purpose of the 2014 Takeda/Sucampo-Par Agreement in multiple ways. Sucampo's

press release/Form 8-K filing announcing the agreement on October 9, 2014 informed the S.E.C. and the public that Par received a “non-exclusive” license to commercialize an AG, when in reality the agreement was structured to ensure Par’s exclusivity; represented that Sucampo and Par “split” the proceeds, when in reality they agreed to a declining royalty structure designed to compensate Par for delaying its generic entry; and omitted crucial details on the parties’ agreed royalty rates.

231. Sucampo’s inclusion of the written Hatch-Waxman settlement agreement in its quarterly S.E.C. filing on November 7, 2014 was calculated to provide the impression of transparency. However, this disclosure, too, was carefully redacted to withhold public notice of the declining royalty rates that ensured Par’s generic exclusivity and constituted an unlawful reverse payment in exchange for generic delay.²⁵

232. Finally, later that same month, Takeda, Par, and Sucampo falsely represented in a public court filing that their Agreement had “procompetitive value” for “consumers.” *Sucampo AG v. Anchen Pharms., Inc.*, No. 13-202 (D. Del.), ECF Nos. 119-1, 121.

233. Premera had no notice, and no way of obtaining notice, of the anticompetitive nature of Takeda and its co-conspirators’ scheme and its own resulting injury until January 2021, when Par launched its AG without any competition from Sucampo or any other licensee.

234. With the information publicly available prior to January 2021, Premera had no way of discovering the nature of the scheme through the exercise of reasonable diligence.

²⁵Sucampo Pharmaceuticals, Inc., Quarterly Report (Form 10-Q), at Ex. 10.2 (Nov. 7, 2014), *available at* https://www.sec.gov/Archives/edgar/data/1365216/000117184314005351/f10q_110614.htm (last accessed April 20, 2023).

235. As a result of Takeda and its co-conspirators' fraudulent concealment, all applicable statutes of limitations affecting Premera's and the Class members' claims have been tolled.

CLASS ACTION ALLEGATIONS

236. Plaintiff Premera brings this action as a class action under Federal Rule of Civil Procedure 23(a) and (b)(3), for itself and on behalf of a Class defined as follows:

All entities that indirectly purchased or paid for some or all of the purchase price of Amitiza and/or AB-rated generic versions of Amitiza in Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, from any of the Defendants or any other generic manufacturer, or their subsidiaries or affiliates, from July 17, 2015, through and until the anticompetitive effects of Defendants' conduct cease (the "Class Period").

237. This Class definition excludes: (a) natural person consumers; (b) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (c) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (d) all persons or entities who purchased Amitiza or its AB-rated generic for purposes of resale from any of the Defendants or any generic manufacturer; (e) fully insured health plans (i.e., health plans that purchased insurance covering 100% of their obligation to members); and (f) pharmacy benefit managers.

238. Members of the Class are so numerous and geographically dispersed that joinder is impracticable.

239. Premera's claims are typical of the claims of Class members. Premera and all Class members were damaged by the same wrongful conduct of the Defendants, i.e., they paid,

and continue to pay, supracompetitive prices for Amitiza and generic Amitiza and were deprived of earlier and more robust competition from cheaper generic versions of Amitiza.

240. Premera will fairly and adequately protect and represent the interests of the Class. Premera's interests are coincident with, and not antagonistic to, those of the Class.

241. Premera is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

242. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to all Class members, thereby making appropriate overcharge damages with respect to the Class as a whole. Such generally applicable conduct is inherent in Defendants' wrongful conduct. The common questions include:

- a. Whether Defendants and their co-conspirators conspired to delay generic competition for Amitiza;
- b. Whether the 2014 Takeda/Sucampo-Par Agreement included a reverse payment;
- c. Whether the reverse payment was large and unexplained;
- d. Whether the reverse payment harmed competition;
- e. Whether Takeda and Par unlawfully maintained market power as a result of the 2014 Takeda/Sucampo-Par Agreement;
- f. Whether there exist any legitimate procompetitive reasons for some or all of Defendants' conduct;
- g. To the extent such reasons exist, whether there existed less restrictive means of achieving them;
- h. Whether the law requires definition of a relevant market when direct proof of market power is available;
- i. If the law does not so require, whether direct proof of Takeda and Par's market power is available;
- j. If the law does so require, the definition of the relevant market;
- k. Whether, before January 1, 2021, Takeda possessed the ability to control prices and/or exclude competition for Amitiza;

- l. Whether Defendants' conduct was a substantial contributing factor in causing some amount of the delay of the entry of AB-rated generic Amitiza or in causing some amount of the delay of the entry of multiple competing AB-rated generic Amitiza products;
- m. Determination of a reasonable estimate of the amount of delay caused by Defendants' conduct;
- n. Whether, and if so to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Premera and the Class;
- o. The quantum of overcharges paid by the Class; and
- p. The appropriate Class-wide measure of damages.

243. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

244. Premera knows of no special difficulty to be encountered in litigation of this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

COUNT I

Conspiracy and Combination in Restraint of Trade Under State Law (Against All Defendants)

245. Premera incorporates by reference the preceding allegations.

246. Premera and the Class indirectly purchased Amitiza and generic Amitiza.

247. Takeda, Sucampo, and Par entered into an agreement or combination in restraint of trade in violation of many states' laws. Takeda, Sucampo, and Par accomplished this scheme by, inter alia, (1) entering into an illegal agreement to delay the entry of generic Amitiza in order

to lengthen the period in which Takeda and Sucampo's brand partnership could monopolize the market and make supracompetitive profits; and (2) illegally agreeing to maintain Par's generic exclusivity for 180 days and up to two years, thereby forestalling the meaningful price competition that results from a multiple-generic market.

248. The 2014 Takeda/Sucampo-Par Agreement constitutes horizontal market allocation and is prohibited by state antitrust laws. The Agreement is a presumptively anticompetitive reverse payment settlement, subject to "quick look" rule of reason scrutiny, because Sucampo provided substantial consideration in exchange for Par's agreement to delay market entrance, and Takeda benefitted from its exercise of market power by maintaining supracompetitive prices.

249. Takeda and its co-conspirators allocated sales of brand Amitiza from July 17, 2015 until January 1, 2021. Takeda and its co-conspirators allocated sales of generic Amitiza from January 1, 2021 until January 1, 2023.

250. There is no procompetitive justification for the anticompetitive Agreement challenged here. The harm to Premera and other payers in the form of paying inflated prices for brand and generic Amitiza outweighs any purported procompetitive justification for the Agreement.

251. Premera and the Class paid artificially inflated prices for Amitiza, including by assignment. There is and was no non-pretextual justification for Takeda and its co-conspirators' anticompetitive actions.

252. As a direct and proximate result of Takeda and its co-conspirators' conduct, as alleged herein, Premera and the Class were injured.

253. By engaging in the foregoing conduct, Takeda and its co-conspirators entered into agreements or contracts in restraint of trade in the relevant market in violation of the following state laws:

- a. Ala. Code § 6-5-60(a), with respect to purchases of Amitiza or generic Amitiza in Alabama.
- b. Arizona Rev. Stat. § 44-1402 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Arizona.
- c. Cal. Bus. & Prof. Code §§ 16700 and 17200 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in California.
- d. D.C. Code § 28-4502 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in the District of Columbia.
- e. Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Florida.
- f. Hawaii Code § 480-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Hawaii.
- g. 740 Ill. Comp. Stat. 10/3 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Illinois.
- h. Iowa Code § 553.4 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Iowa.
- i. Kansas Stat. Ann. § 50-101 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Kansas.
- j. Md. Com'l Law Code Ann. § 11-204(a) *et seq.*, with respect to Amitiza or generic Amitiza in Maryland.
- k. Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Maine.
- l. Mich. Comp. Laws Ann. § 445.772 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Michigan.
- m. Minn. Stat. Minn. Stat. § 325D.53 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Minnesota.
- n. Miss. Code Ann. § 75-21-3 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Mississippi.
- o. Neb. Code Ann. § 59-801 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Nebraska.
- p. Nev. Rev. Stat. Ann. § 598A.060 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Nevada.

- q. N.M. Stat. Ann. § 57-1-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in New Mexico.
- r. N.Y. Gen. Bus. Law § 340 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in New York.
- s. N.C. Gen. Stat. § 75-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in North Carolina.
- t. N.D. Cent. Code § 51-08.1-02 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in North Dakota.
- u. Or. Rev. Stat. § 646.725 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Oregon.
- v. R.I. Gen. Laws § 6-36-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Rhode Island.
- w. S.D. Codified Laws § 37-1-3.1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in South Dakota.
- x. Tenn. Code Ann. § 47-25-101 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Tennessee.
- y. Utah Code Ann. § 76-10-3103 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Utah.
- z. Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Vermont.
- aa. Wis. Stat. § 133.03 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Wisconsin.

COUNT II

Monopolization Under State Law

(Against All Defendants)

- 254. Premera incorporates by reference the preceding allegations.
- 255. Premera and the Class indirectly purchased Amitiza and generic Amitiza.
- 256. Takeda and its co-conspirators monopolized trade by, inter alia, (1) entering into an illegal agreement to delay the entry of generic Amitiza in order to lengthen the period in which Takeda and Sucampo's brand partnership could monopolize the market and make supracompetitive profits; and (2) illegally agreeing to maintain Par's generic exclusivity for 180

days and up to two years, thereby forestalling the meaningful price competition that results from a multiple-generic market.

257. Takeda and its co-conspirators joined in and participated in the 2014 Takeda/Sucampo-Par Agreement alleged above and received the benefits of the Agreement.

258. Takeda and its co-conspirators allocated sales of brand Amitiza from July 17, 2015 until January 1, 2021. Takeda and its co-conspirators allocated sales of generic Amitiza from January 1, 2021 until January 1, 2023.

259. There is no procompetitive justification for the anticompetitive Agreement challenged here. The harm to Premera and other payers in the form of paying inflated prices for brand and generic Amitiza outweighs any purported procompetitive justification for the Agreement.

260. Premera and the Class paid artificially inflated prices for Amitiza, including by assignment. There is and was no non-pretextual justification for Defendants' anticompetitive actions.

261. As a direct and proximate result of Takeda and its co-conspirators' conduct, as alleged herein, Premera and the Class were injured.

262. By engaging in the foregoing conduct, Takeda and its co-conspirators have intentionally and wrongfully monopolized trade in violation of the following state laws:

- a. Ala. Code § 6-5-60(a) *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Alabama.
- b. Arizona Rev. Stat. § 44-1402 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Arizona.
- c. Cal. Bus. & Prof. Code §§ 16700 and 17200 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in California.

- d. D.C. Code § 28-4502 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in the District of Columbia.
- e. Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Florida.
- f. Hawaii Code § 480-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Hawaii.
- g. 740 Ill. Comp. Stat. 10/3 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Illinois.
- h. Iowa Code § 553.4 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Iowa.
- i. Kansas Stat. Ann. § 50-101 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Kansas.
- j. Md. Com'l Law Code Ann. § 11-204(a) *et seq.*, with respect to Amitiza or generic Amitiza in Maryland.
- k. Me. Rev. Stat. Ann. 10, § 1101 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Maine.
- l. Mich. Comp. Laws Ann. § 445.772 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Michigan.
- m. Minn. Stat. Minn. Stat. § 325D.53 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Minnesota.
- n. Miss. Code Ann. § 75-21-3 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Mississippi.
- o. Neb. Code Ann. § 59-801 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Nebraska.
- p. Nev. Rev. Stat. Ann. § 598A.060 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Nevada.
- q. N.M. Stat. Ann. § 57-1-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in New Mexico.
- r. N.Y. Gen. Bus. Law § 340 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in New York.
- s. N.C. Gen. Stat. § 75-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in North Carolina.
- t. N.D. Cent. Code § 51-08.1-02 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in North Dakota.
- u. Or. Rev. Stat. § 646.725 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Oregon.

- v. R.I. Gen. Laws § 6-36-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Rhode Island.
- w. S.D. Codified Laws § 37-1-3.1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in South Dakota.
- x. Tenn. Code Ann. § 47-25-101 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Tennessee.
- y. Utah Code Ann. § 76-10-3103 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Utah.
- z. Vt. Stat. Ann. 9, § 2453 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Vermont.
- aa. Wis. Stat. § 133.03 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Wisconsin.

COUNT III

Unfair and Deceptive Trade Practices Under State Law (Against All Defendants)

263. Premera incorporates by reference the preceding allegations

264. Premera and the Class indirectly purchased Amitiza and generic Amitiza.

265. Takeda and its co-conspirators engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. The conduct that is common to all of the deceptive practices causes of action is that Defendants harmed Premera and the Class by (1) entering into an illegal agreement to delay the entry of generic Amitiza in order to lengthen the period in which Takeda and Sucampo's brand partnership could monopolize the market and make supracompetitive profits; and (2) illegally agreeing to maintain Par's generic exclusivity for 180 days and up to two years, thereby forestalling the meaningful price competition that results from a multiple-generic market. *See MacQuarie Grp. Ltd. v. Pac. Corporate Grp., LLC*, 2009 U.S. Dist. LEXIS 16554, at *23-25 (S.D. Cal. Mar. 2, 2009) ("courts routinely treat[] antitrust violations as deceptive acts").

266. Defendants' conduct had a substantial effect on the business operations of Premera and Class members in these states because Premera and members of the Class purchased at pharmacies located in these states.

267. As a direct and proximate result of Defendant's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Premera and the Class were deprived of the opportunity to purchase generic versions of Amitiza and forced to pay artificially inflated prices for these drugs.

268. There was a gross disparity between the price that Premera and the Class paid for brand and generic Amitiza, and the value received, given that a much cheaper substitute generic product should have been available earlier, and prices for Amitiza should be much lower and should have decreased at an earlier point, but for Takeda and its co-conspirators' unlawful scheme.

269. To the extent necessary under the state consumer protection statutes listed below, Premera and the Class relied on Takeda and its co-conspirators' candor in representing the state of competition for Amitiza and generic Amitiza in making purchasing decisions and in negotiating contracts (including rebates) with Takeda for Amitiza or generic Amitiza purchases made to benefit its insureds.

270. By engaging in the foregoing conduct, Defendants have engaged in in unfair competition or deceptive acts and practices in violation of the following state laws:

- a. Alaska stat. § 45.50.471 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Alaska;
- b. Ariz. Code § 44-1522 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Arizona;
- c. Cal. Civil Code § 1750 *et seq.* and Cal. Bus. & Prof. Code § 17200 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in California;
- d. Conn. Gen. Stat. § 6-1-105 *et seq.*, with respect to purchases of Amitiza or generic

Amitiza in Connecticut;

- e. D.C. Code § 28-3901 *et seq.*, with respect to the purchases of Amitiza or generic Amitiza in the District of Columbia;
- f. Fla. Stat. § 501.201 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Florida;
- g. Idaho Code § 48-601 *et seq.*, with respect to the purchases of Amitiza or generic Amitiza in Idaho;
- h. 815 ILCS § 505/1 *et seq.*, with respect to the purchases of Amitiza or generic Amitiza in Illinois;
- i. Kan. Stat. § 50-623 *et seq.*, with respect to the purchases of Amitiza or generic Amitiza in Kansas;
- j. 5 Me. Rev. Stat § 207 *et seq.*, with respect to the purchases of Amitiza or generic Amitiza in Maine;
- k. Mass. Gen. L. Ch. 93A *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Massachusetts;
- l. Mich. Stat § 445.901 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Michigan;
- m. Minn. Stat. § 325D.43 *et. seq.*, Minn. Stat. § 325F.69 *et seq.*, and Minn. Stat. § 8.31 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Minnesota;
- n. Missouri Stat § 407.010 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Missouri;
- o. Neb. Rev. Stat. § 59-1601 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Nebraska;
- p. Nev. Rev. Stat. § 598.0903 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Nevada;
- q. N.H. Rev. Stat. § 358~A:1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in New Hampshire;
- r. N.J. Rev. Stat § 56:8-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in New Jersey;
- s. N.M. Stat. § 57-12-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in New Mexico;
- t. N.Y. Gen. Bus. Law § 349 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in New York;
- u. N.C. Gen. Stat. § 75-1.1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in North Carolina;
- v. Okla. Stat. tit. 15, § 751 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Oklahoma;

- w. Or. Rev. Stat. § 646.605 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Oregon;
- x. 73 Pa. Stat. Ann. § 201-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Pennsylvania;
- y. S.D. Code Laws § 37-24-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in South Dakota;
- z. Utah Code § 13-11-1 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Utah;
- aa. 9 Vt. § 2451 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Vermont;
- bb. Va. Code Ann. § 59.1-100096 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Virginia;
- cc. W. Va. Code § 46A-6-101 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in West Virginia; and
- dd. Wis. Stat. § 100.18; Wis. Stat. § 100.20 *et seq.*, with respect to purchases of Amitiza or generic Amitiza in Wisconsin.

COUNT IV

Unjust Enrichment Under State Law

(Against All Defendants)

- 271. Premera incorporates by reference the preceding allegations.
- 272. Premera and the Class indirectly purchased Amitiza and generic Amitiza.
- 273. Premera and the Class seek unjust enrichment under the laws of the states and territories of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

274. The conduct that is common to all unjust enrichment causes of action is that Takeda and its co-conspirators harmed Premera and the Class by (1) entering into an illegal agreement to delay the entry of generic Amitiza in order to lengthen the period in which Takeda and Sucampo's brand partnership could monopolize the market and make supracompetitive profits; and (2) illegally agreeing to maintain Par's generic exclusivity for 180 days and up to two years, thereby forestalling the meaningful price competition that results from a multiple-generic market.

275. Defendants have benefitted from monopoly profits on the sale of Amitiza resulting from the unlawful and inequitable acts alleged in this Complaint.

276. Defendants' financial benefit resulting from their unlawful and inequitable acts is traceable to overpayments for Amitiza and generic Amitiza by Premera and the Class.

277. Premera and the Class have conferred upon Defendants an economic benefit, profits from unlawful overcharges and monopoly profits to the economic detriment of Premera and the Class.

278. It would be futile for Premera and the Class to seek a remedy from any party with whom it has privity of contract with for its purchases of Amitiza and generic Amitiza.

279. It would be futile for Premera and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Amitiza or generic Amitiza, as it is not liable and would not compensate Premera or the Class for unlawful conduct caused by Defendants.

280. The economic benefit of overcharges and monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Amitiza and generic Amitiza is a direct and proximate result of Defendants' unlawful conduct.

281. The economic benefits derived by Defendants rightfully belongs to Premera and the Class, as they paid anticompetitive and monopolistic prices between July 17, 2015 and the present (and continuing), all of which benefited Defendants.

282. It would be inequitable under unjust enrichment principles under the law of the District of Columbia, Puerto Rico, and the laws of all states in the United States, except Ohio and Texas, for Defendants to be permitted to retain any of the overcharges for Amitiza and generic Amitiza derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

283. Defendants are aware of and appreciate the benefits bestowed upon them by Premera and the Class.

284. Defendants should be compelled to disgorge in a common fund for the benefit of Premera and the Class all unlawful or inequitable proceeds they received.

285. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Premera and the Class.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff Premera Blue Cross demands judgment against Defendants, as follows:

1. Awarding Plaintiff and the Class actual, consequential, compensatory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post-judgment interest at the statutory rates.
2. Awarding Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment.
3. Awarding Plaintiff its reasonable costs and expenses, including attorneys' fees; and
4. Awarding all other legal or equitable relief as the Court deems just and proper.

XIV. JURY DEMAND

Plaintiff demands a jury trial on all claims so triable.

DATED: June 2, 2023

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[Pro hac vice motions are forthcoming.]